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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/046,504	10/19/2001	Steven J. Siegel	PENN-0789	3358

7590 11/16/2005

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EXAMINER	
FUBARA, BLESSING M	
ART UNIT	**PAPER NUMBER**
1618	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/046,504	SIEGEL ET AL.	
	Examiner	Art Unit	
	Blessing M. Fubara	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges receipt of request for continued examination under 37 CFR 1.114, amendment and remarks filed 10/07/05. Claims 1-10 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 10/07/05 has been entered.

Applicants' Remarks:

Applicants argue that Kino and Cheng teach microspheres while Brodbeck teaches viscous liquid; that the structural difference is that the claims product is compression molded and that neither of the prior art references disclose single compression molded implant.

2. Applicants' arguments filed 10/07/05 have been fully considered but they are not persuasive.

The references disclose and suggest implantation of the composition/product and there does not appear to be structural difference that lends to d not structural difference According to MPEP 2113 [R-1] product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or

obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). In this case, the product consists essentially of haloperidol and biodegradable polymer, which is disclosed by the cited references.

Claim Rejections - 35 USC § 102

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. Claims 1 and 2 are rejected under 35 U.S.C. 102(b) as being anticipated by Kino et al. (WO 94/10982, English abstract).

Kino discloses an implantable system that comprises haloperidol and lactic acid/glycolic acid copolymer (abstract). Kino meets the limitations of the claims.

5. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Cheng et al. (J. Controlled Release, 1988, 203-212).

Cheng discloses a delivery system that comprises haloperidol and 50:50 lactide-glycolide copolymer (section 2. 1). Cheng loads haloperidol onto lactide-glycolide copolymer in the presence of the organic solvent, dichloromethane, emulsifies the mixture and the solvent is evaporated off to produce microspheres (section 2.2). Cheng discloses in the introduction that haloperidol is useful in the treatment of schizophrenia. "Surgically implantable" in claim 1 is a future intended use and future intended carries no patentable weight in a composition claim. Thus, Cheng meets the limitations of the claims.

6. Claims 1-6 are rejected under 35 U.S.C. 102(e) as being anticipated by Brodbeck et al. (US 6,130,200).

Brodbeck discloses "methods and compositions for systemically or locally administering by implantation a beneficial agent to a subject" (abstract). Haloperidol is one of the beneficial agents in Brodbeck (column 20, line 23). The composition comprises 50:50 poly (lactide-co-glycolide) copolymers and in the preparation solvents are involved (column 5, lines 24-56). Brodbeck discloses treating by implanting a delivery system comprising a beneficial agent (column 4, lines 57-64) and the system is the haloperidol-poly (lactide-co-glycolide) copolymer delivery system described above. An implant has the option of being removable since a surgically implanted device can also be removed surgically. Since the carrier is biodegradable, the removal would depend on when the removal is initiated before the carrier is completely degraded. Brodbeck meets the limitations of the claims.

Claim Rejections - 35 USC § 103

7. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

8. Claims 4-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheng et al. ((J. Controlled Release, 1988, 203-212).

Cheng discloses a method of preparing delivery device that comprises poly(lactide-co-glycolide) copolymer microspheres, organic solvent such as dichloromethane, polyvinyl alcohol by a process of emulsification-solvent evaporation (section 2). The difference between Cheng and the instant claims is that Cheng does not specifically state that the composition is formulated as an implant. But in lines 3-7 of column 2, page 204, Cheng discloses that the composition can be implanted. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare haloperidol-poly(lactide-co-glycolide) copolymer

composition. One having ordinary skill in the art would have been motivated to formulate the composition into an implant with the expectation of improving the degree of compliance and more predictable absorption. An implant has the option of being removable since a surgically implanted device can also be removed surgically. Since the carrier is biodegradable, the removal would depend on when the removal is initiated before the carrier is completely degraded.

9. Claims 7-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brodbeck et al. (US 6,130,200).

Brodbeck discloses implanting composition comprising haloperidol and poly(lactide-co-glycolide) copolymer to treat a subject in need thereof. Brodbeck does not disclose treating psychotic conditions. However, it is known that haloperidol is an antipsychotic agent (see Kino, WO 94/10982, abstract, as a teaching reference). The method of claim 7 administers and the prior art administers by implantation. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to implant the haloperidol composition in a subject in need of treatment. One having ordinary skill in the art would have been motivated to implant the haloperidol composition with the expectation of treating psychosis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600